[ORAL ARGUMENT NOT YET SCHEDULED]

No. 24-5290

United States Court of Appeals for the District of Columbia Circuit

ARDELYX, INC.; AMERICAN ASSOCIATION OF KIDNEY PATIENTS; NATIONAL MINORITY QUALITY FORUM,

Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, ADMINISTRATOR OF CENTERS FOR MEDICARE AND MEDICAID SERVICES; CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Columbia
No. 1:24-cv-02095-BAH (Hon. Beryl A. Howell)

FINAL REPLY BRIEF OF PLAINTIFFS-APPELLANTS

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GLOSSARY

CMS	Centers for Medicare and Medicaid Services
ESA	Erythropoiesis Stimulating Agent
ESRD	End Stage Renal Disease
GAO	Government Accountability Office
GB	Government Brief
MIPPA	Medicare Improvements for Patients and Providers Act
OB	Opening Brief
TDAPA	Transitional Drug Add-on Payment Adjustment

INTRODUCTION

The Government admits that by enacting the Medicare Improvements for Patients and Providers Act ("MIPPA"), Pub. L. No. 110-275, 122 Stat. 2494 (2008), Congress intended to create a "new bundled payment system" for the cost-efficient provision of "*renal dialysis* services" by "*dialysis facilities*." Government Brief ("GB") 2, 25, 34 (emphasis added). The Government does not dispute, however, that oral-only drugs like Ardelyx's drug XPHOZAH are not provided during renal dialysis, nor by "dialysis facilities." Unsurprisingly, therefore, Congress excluded oral-only drugs from MIPPA's four enumerated categories of "renal dialysis services." The Government's insistence that such drugs are "renal dialysis services" regardless cannot be squared with MIPPA's text or purpose.

The Government principally claims that oral-only drugs fall within 42 U.S.C. § 1395rr(b)(14)(B)(iii)—in which Congress addressed the kinds of drugs that would qualify as "renal dialysis services." But Congress specifically elected not to include all oral drugs within subpart (B)(iii)—only those that are the "oral equivalent form" of drugs and biologicals furnished by renal dialysis providers. In defending the district court's contrary reading, the Government advances an implausible interpretation of subpart (B)(iii) that violates bedrock principles of statutory construction, conflicts with CMS's own contemporaneous construction, and cannot be reconciled with Congress's aim in creating the bundled payment system. Indeed,

the Government's interpretation would *eject* from the bundled payment system drugs that have long been included.

The Government also half-heartedly suggests that oral-only drugs might fall within § 1395rr(b)(14)(B)(iv). But it does not contest that its reading of that provision would render subparts (B)(ii) and (B)(iii) superfluous and render meaningless the highly nuanced definition of (B)(iii) that it insists Congress intended to enact. So that's a non-starter as well. Perhaps because it recognizes that oral-only drugs do not fall "neatly into the subparagraph (B) clauses," GB40, the Government finally muses that CMS might be free to add its own categories of "renal dialysis services" to those selected by Congress. That too is wrong. Congress was clear that MIPPA's bundled payment system consists of "renal dialysis services (*as defined in subparagraph (B)*)"—not as expanded through regulation by CMS. 42 U.S.C. § 1395rr(b)(14)(A)(i) (emphasis added). So the Government cannot rely on some freestanding power to reshape the balance Congress struck. In short, the Government's interpretation is not the "best reading" of MIPPA. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024). It should be rejected.

The Government also argues that this Court lacks authority to stop the agency from exceeding Congress's statutory limits. But this Court has repeatedly held in similar cases that a provision precluding judicial review "extends no further than the Secretary's statutory authority to" take the action. *Amgen, Inc. v. Smith*, 357 F.3d

103, 112 (D.C. Cir. 2004). Because CMS lacked statutory authority to expand upon Congress's definition of "renal dialysis services," this Court has authority to step in.

The Government's inclusion of oral-only drugs in MIPPA's bundled payment system is not only wrong as a matter of law, but also bad for ESRD patients. Past experience shows that when new drugs are included in the bundle, their use drops dramatically. Forcing oral-only drugs into an already overburdened bundled payment system will deter uptake of needed treatments, harm patients, and disincentivize drug manufacturers from developing novel ESRD treatments. That is why dozens of organizations have warned CMS against placing oral-only drugs into the bundled payment system—and why key stakeholders advocating for ESRD patients have joined Ardelyx in this suit, not the Government.

CMS's oral-only policy cannot be squared with MIPPA's text and purpose. This Court should reverse and grant summary judgment to Plaintiffs.

SUMMARY OF ARGUMENT

I. This Court has jurisdiction to reach the merits of Plaintiffs' claims for two independent reasons. First, as the district court found, whether this court has jurisdiction turns on whether CMS's action falls within its statutory authority. Because CMS lacks authority to alter Congress's definition of "renal dialysis services," jurisdiction and the merits merge. Second, Congress did not preclude challenges to *regulations* redefining the reach of "renal dialysis services."

II. On the merits, the district court erred in holding that CMS's oral-only policy was lawful. Oral-only drugs are not "renal dialysis services" under MIPPA's text, which lays out four non-overlapping categories, none of which include oral-only drugs. Lacking textual support, CMS appeals to subsequent enactments that delayed the implementation of CMS's policy. But these actions demonstrate congressional caution regarding CMS's policy, not endorsement. And CMS's appeals to policy are tone-deaf, ignoring real-world evidence showing that including oral-only drugs in the bundle will harm patients.

III. Even if oral-only drugs generally count as "renal dialysis services," XPHOZAH in particular cannot because it is not furnished for the treatment of ESRD. It instead treats hyperphosphatemia.

ARGUMENT

I. THE PRECLUSION PROVISION DOES NOT BAR REVIEW OF THE MERITS

A. Jurisdiction And The Merits Merge

The Government argues that 42 U.S.C. § 1395rr(b)(14)(G) bars review of Plaintiffs' claim. But Plaintiffs allege that CMS has exceeded its statutory authority by redefining "renal dialysis services" to include oral-only drugs. Opening Brief ("OB") 30-35. In such cases, as the district court recognized, preclusion of review "extends no further than the Secretary's statutory authority" to take the action challenged in this case. JA168 (Mem. Op. Granting Mot. Dismiss ("MTD Op.") 14

(Dkt. 22)) (quoting *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004)). If this Court finds that CMS "has acted outside the scope of its statutory mandate," then "[it] ha[s] jurisdiction." *Am. Hosp. Ass'n v. Azar* , 964 F.3d 1230, 1238 (D.C. Cir. 2020) (citation omitted). "As a practical matter, then, the court can simply skip to the merits question in its analysis." *Id.*; *see also Amgen*, 357 F.3d at 111-14. In effect, "[t]he jurisdictional question here … merges with … the merits." JA169 (MTD Op. 15).

CMS tries to distinguish *Amgen* and *American Hospital Association* on the sole theory that the jurisdiction-stripping provisions in those cases featured an "express[] cross-reference[]" to the statutory definition in question and the preclusion provision here does not. GB31-32. But as the district court explained, that is a distinction without a difference, and "*Amgen* is more similar to this case than defendants admit." JA171 (MTD Op. 17). *Amgen*'s definitional subparagraph was "absent from the preclusion subparagraph" there, and "lack[ed] any explicit link" between the two. JA171-72 (MTD Op. 17-18). Yet *Amgen* concluded that part of the definitional subparagraph "was implicitly linked" to the preclusion provision, and then analyzed whether the agency had exceeded its authority. JA172 (MTD Op. 18); *see Amgen*, 357 F.3d at 112-13.

Like *Amgen*, the district court found the "link" between "the definitional subparagraph (B)" and the "preclusion subparagraph (G)" to be "sufficiently

implied" here. JA172 (MTD Op. 18). And it concluded that "it would be reductive to conclude from subparagraph (G)'s absence of three words, 'under subparagraph (B),' that Congress intended for its definition of 'renal dialysis services' to be unenforceable, especially in light of the presumption of judicial review." *Id.*

CMS *nowhere* addresses the district court's analysis. *See generally* GB31-33. Nor does CMS squarely face the effect of its position, which would preclude from review any "determination *purporting* to be an identification of a renal dialysis service," no matter how far outside the agency's statutory authority. JA169 (MTD Op. 15). That would enable CMS to prevent review of a decision to treat *all* drugs as "renal dialysis services" (including those that treat asthma, HIV, or arthritis). *See* OB33-34. It is "preposterous" that Congress intended such results. *COMSAT Corp. v. FCC*, 114 F.3d 223, 227 (D.C. Cir. 1997). Under settled precedent, jurisdiction and the merits merge in this case.

B. Section 1395rr(b)(14)(G) Does Not Reach Plaintiffs' Challenge To The Regulation

Alternatively, the preclusion provision does not apply because it merely limits judicial review of CMS's "identification of renal dialysis services included in the bundled payment;" it does not prevent a challenge to a regulation purporting to expand the definition of renal dialysis services. OB28-30; *see* 42 U.S.C. § 1395rr(b)(14)(G).

CMS first implies that Plaintiffs challenge only the letter designating XPHOZAH as a renal dialysis service, not the regulation on which that letter was based. GB26-27. That is wrong. Plaintiffs' complaint clearly challenged the underlying regulation. JA55 (Compl. ¶¶ 212-15 (Dkt. 1)). In particular, Plaintiffs alleged that CMS's "definition of 'Renal dialysis services' at 42 CFR 413.171(3)" was in "excess of statutory jurisdiction and authority" and sought an order "vacating and setting [it] aside" and "enjoining" its application to oral-only drugs. JA55 (Compl. ¶ 215); JA57 (Compl. at 50); *see also* JA29-34 (Compl. ¶¶ 87-108).

CMS next argues that the term "identification" is "sufficiently broad" to encompass both the identification of particular "renal dialysis services," as well as a regulation altering the definition of that term. GB27-28 (quoting JA167 (MTD Op. 13)). But CMS's regulation did not identify any particular "services included in the bundled payment." 42 U.S.C. § 1395rr(b)(14)(G); *see* OB28-30. Indeed, CMS itself admits that the regulation expressly "leaves open the question of whether a particular oral-only drug comes within the category of oral-only drugs that can be included in the renal dialysis services bundle." GB30-31. As such, Plaintiffs' challenge to CMS's regulation does not fall within the scope of § 1395rr(b)(14)(G).

Even if "identification" was sufficiently broad to make CMS's reading of § 1395rr(b)(14)(G) "plausible," the text "does not compel it." *Am. Clinical Laboratory Ass'n v. Azar*, 931 F.3d 1195, 1205 (D.C. Cir. 2019). As a result, the

preclusion provision cannot apply. The "'strong presumption'" favoring judicial review "can only be overcome by a 'clear and convincing evidence' that Congress intended to preclude the suit." *Amgen*, 357 F.3d at 111 (citations omitted). When a statute is "reasonably susceptible" to multiple interpretations, courts "adopt the reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review." *Am. Clinical Laboratory Ass'n*, 931 F.3d at 1204 (citation omitted).

CMS also argues that Plaintiffs' challenge to the regulation is "inextricably intertwined" with their challenge to the identification of XPHOZAH as a renal dialysis service. GB30-31. But the regulation is a separate agency action that predated CMS's identification of XPHOZAH as a renal dialysis service by over a decade. The Administrative Procedure Act authorizes Plaintiffs to separately challenge that regulation. 5 U.S.C. §§ 702, 704; *see Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 603 U.S. 799, 807-08 (2024).

Moreover, § 1395rr(b)(14)(G) cross-references two sections—42 U.S.C. §§ 1395oo and 1395ff—covering "administrative appeals by patients or providers who wish to contest a coverage determination or reimbursement amount." *Am. Clinical Laboratory Ass'n*, 931 F.3d at 1205; *compare* 42 U.S.C. § 1395m-1(h)(1) (precluding review "under section 1395ff of this title, section 1395oo of this title, or otherwise"), *with* 42 U.S.C. § 1395rr(b)(14)(G) (same). Those cross-references

reinforce that Congress intended to preclude review of decisions about Medicare's payment for particular renal dialysis services "but not to prevent review of [a] rule" that "inform[s]" those individual decisions. *Am. Clinical Laboratory Ass'n*, 931 F.3d at 1205.

II. ORAL-ONLY DRUGS ARE NOT "RENAL DIALYSIS SERVICES"

Congress chose not to include oral-only drugs within MIPPA's statutory definition of "renal dialysis services." CMS long ago admitted that the statute can be read to exclude oral-only drugs, but disagreed with that interpretation as a matter of policy. But the Government's current alternative construction of the statute is wholly implausible—resulting in a nonsensical patchwork of coverage, and either negating or rendering superfluous substantial portions of Congress's definition.

Unable to defend its interpretation on MIPPA's text or purpose, the Government appeals to later legislation and policy. But the Government significantly overreaches in relying on those arguments, which often cut against it and cannot bridge the gap between its implausible, post-hoc construction and MIPPA's text and purpose.

A. The Text Of The Statute Excludes Oral-Only Drugs

Oral-only drugs that are provided neither during dialysis nor by dialysis facilities are not "renal dialysis services" under MIPPA's text, which lays out four non-overlapping categories. 42 U.S.C. § 1395rr(b)(14)(B); *see* OB37-43, 47-52.

CMS concedes that oral-only drugs do not come within either subpart (B)(i) or subpart (B)(ii). Nor, as Plaintiffs have explained, do they come within subpart (B)(iii) or subpart (B)(iv). *See* OB37-52. And neither the prefatory word "includes" nor the express exclusion of "vaccines" confers free-floating authority on CMS to add oral-only drugs to the bundle.

Subpart (B)(iii). Subpart (B)(iii) defines two different groups of drugs as "renal dialysis services": first, "other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter," and, second, "any oral equivalent form of such drug or biological." 42 U.S.C. § 1395rr(b)(14)(B)(iii). Properly understood, the first group includes the injectable drugs and biologicals that dialysis facilities administer during dialysis; the second group covers the oral equivalent form of those injectable drugs and biologicals. *See* OB38-40, 51-52. Neither includes oral-only drugs.

CMS's attempt to avoid that conclusion requires rewriting the statute. In enacting its regulatory definition of renal dialysis services, CMS rewrote the latter half of subpart (B)(iii), transforming the statute's direction to include "any *oral equivalent form* of such drug or biological" into "drugs and biologicals with *only an oral form*." 42 C.F.R. § 413.171(3) (emphasis added). CMS took that step as a matter of policy, not legal interpretation. Recognizing that this phrase could be

limited to "only oral versions of injectables," it rejected that reading as "unduly constrained." 74 Fed. Reg. 49922, 49928 (Sept. 29, 2009). Yet the constraint is of the text's own making: for a drug to be an "oral equivalent form," there has to be some other, non-oral form of that drug. Otherwise, there is nothing to which the oral drug could be equivalent. *See, e.g.*, *Equivalent*, *Cambridge Dictionary*, https://dictionary.cambridge.org/us/dictionary/english/equivalent (last visited Mar. 26, 2025) ("equal to or having the same effect as something else"). CMS nonetheless chose to "rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014); *see* OB38-40.

CMS suggests that oral drugs fall within the first half of (B)(iii). But interpreting the first half of (B)(iii) as the Government proposes would render the second half of (B)(iii) entirely superfluous. Put simply, there would be no need to separately and precisely account for the "oral equivalent forms" of drugs if all oral drugs already fell within (B)(iii)'s first clause.

To get around that superfluity, CMS tries (as the district court did) to suggest that the two parts of (B)(iii) speak to drugs from different times. In particular, it argues that the first clause only adds to the bundle ESRD drugs outside the composite rate system for which payment was made "before the application of this paragraph." CMS then claims that the second part of clause (B)(iii) adds only one kind of "subsequently-developed" ESRD drug—namely "oral versions" of drugs. GB55. In

the Government's telling, therefore, Congress drafted subpart (B)(iii) in a manner that excludes all future ESRD treatments *except* those that are the oral-equivalent form of the older drugs covered by the first part of clause (B)(iii).

In attempting to avoid superfluity, CMS's newfound reading of subpart (B)(iii) leads to a different and more extreme problem: a nonsensical reading that Congress could not have intended. The Government does not contest that its reading of subpart (B)(iii) would result in an inexplicable patchwork of coverage—where only injectable or biological drugs created before January 1, 2011 would fall within subpart (B)(iii), while those coming after would not; the only new drugs that would qualify would be the "subsequently-developed oral versions of drugs, which were extant in a different form at the time (B)(iii) was applied." OB49. That reading would exclude from (B)(iii) many drugs that are currently in the bundle and conflict with CMS's own historical practice. OB49-50. It would also over time increase the share of renal dialysis services furnished by dialysis providers outside the bundle—exactly the result Congress was working to avoid.

Given the history and purpose of MIPPA, it is inconceivable that Congress would have intended that result. *See* OB8-11, 40-41. By contrast, Plaintiffs' reading leads to a much more sensible scheme—one that better accords with the Government's past practice and that comports with the statutory purpose by

including the drugs furnished by dialysis facilities and their oral equivalents, whenever first marketed. OB51-52.[1]

The Government's construction of subpart (B)(iii) is particularly bizarre because it ought to exclude from subpart (B)(iii) novel drugs like XPHOZAH that were never paid for separately "before the application of this paragraph." The district court sought to avoid that consequence by interpreting that clause to mean different dates depending on whether the drug in question is orally administered. On appeal, the Government is noncommittal, suggesting that "the Court need not address the exact metes and bounds of whether the relevant date for the parenthetical was the statute's original effective date of January 1, 2011, or the later effective date of when the statutory provision would be applied to a particular drug[] (or class of drugs) to include them in the bundle." GB54 n.7. But Congress's later actions never altered the application of the *statute*; they instead delayed implementation of CMS's regulatory "*policy*" relating to oral-only drugs. American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 632(b)(1), 126 Stat. 2313, 2354 (2012) (CMS "may not implement the *policy* … relating to oral-only" drugs); Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 217(a), 128 Stat. 1040, 1061 (2014) (referring to "delay of implementation of oral-only *policy*" (capitalization

[1] It is inconceivable that Congress provided only "oral-equivalent" future drugs would satisfy subpart (B)(iii) given that they accounted for negligible cost. 75 Fed. Reg. 49030, 49043 (Aug. 12, 2010).

normalized)); Achieving A Better Life Experience Act of 2014, Pub. L. No. 113-295, div. B, § 204, 128 Stat. 4010, 4065 (2014) (referring to "delay of implementation of oral-only *policy*" (capitalization normalized)) (emphases added).

Thus, CMS's reading erroneously makes the "application" of a *statute* turn on when CMS's *regulation* goes into effect. But CMS does not have the authority to alter MIPPA's applicability. *Util. Air Regul. Grp.*, 573 U.S. at 327 ("[A]uthoriz[ing] an agency to modify unambiguous requirements imposed by a federal statute" would "deal a severe blow to the Constitution's separation of powers."). At most, a regulation can delay the application of an agency's rulemaking or enforcement authority. *Cf. AFGE v. Campbell*, 659 F.2d 157, 158-59 (D.C. Cir. 1980) (statutory provisions "setting an effective date" "prevent excessive agency delay").

The statute also makes clear that the district court was wrong about the meaning of "before the application of this paragraph." "This paragraph" refers to all of 42 U.S.C. § 1395rr(b)(14)—that is, to the bundled payment system put into place by MIPPA. *See* Pub. L. No. 110-275, § 153, 122 Stat. 2494, 2553-56 (2008) (amending 42 U.S.C. § 1395rr(b) "by adding at the end the following new paragraph"). Context makes that clear: Several surrounding provisions refer to "paragraph (14)" or "the system under paragraph (14)." 42 U.S.C. § 1395rr(b)(12)(A), (F); *id.* § 1395rr(b)(13); *id.* § 1395rr(h)(1)(C).

When that paragraph became "applicable" is January 1, 2011, when the bundled payment system went into effect, as multiple provisions within paragraph (14) demonstrate. *See* 42 U.S.C. § 1395rr(b)(14)(A)(i) ("for services furnished on or after January 1, 2011"); *id.* § 1395rr(b)(14)(B)(i) (including "items and services included in the composite rate for renal dialysis services as of December 31, 2010"); *id.* § 1395rr(b)(14)(D)(iii) ("renal dialysis services furnished on or after January 1, 2011"); *id.* § 1395rr(b)(14)(E)(i)-(ii) (referring to "four-year phase-in" ending on "January 1, 2014" and requiring opt-out of phase-in "prior to January 1, 2011"). It is unsurprising that CMS previously interpreted the phrase "before the application of this paragraph" to mean "prior to January 1, 2011." 42 C.F.R. § 413.171(3).

Subpart (B)(iv). Recognizing that its novel interpretation of subpart (B)(iii) might limit its authority to incorporate new drugs into the bundle, CMS falls back on its purported "catchall authority" in subpart (B)(iv) to bring in new drugs that are "not strictly required to be included under (B)(iii)." GB55-56. But subpart (B)(iv) does not save it.

Subpart (B)(iv) includes in the bundle "diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease." 42 U.S.C. § 1395rr(b)(14)(B)(iv). Having just addressed drugs at length in subparts (B)(ii) and (iii), subpart (B)(iv) addresses other renal dialysis services not part of the composite rate system: e.g., laboratory

tests, syringes, specialized tubing, blood, and blood products that "facilities may furnish during the dialysis treatment. *Cf.* 75 Fed. Reg. at 49064.

The Government, by contrast, reads clause (iv) to be a boundless catchall that covers everything not reached by clause (i), "including oral-only drugs[] that are developed after the bundled payment system is first implemented but serve the same function as services already included in the bundle." GB58. In other words, having just insisted that subpart (B)(iii) carefully limits the new drugs that qualify as renal dialysis services to those that are the "oral equivalent form" of pre-2011 injectable drugs and biologicals, CMS then suggests that subpart (B)(iv) undoes that choice entirely.[2]

Reading clause (iv) in that way does not make sense for multiple reasons. For one thing, if clause (iv) was intended as a catch-all for all drugs not reached by clause (i-iii), it would have been written to cover "other items and services not described in *clauses (i)-(iii)*." Instead, clause (iv) is written to cover "diagnostic laboratory tests and other items and services not described in *clause (i)*," 42 U.S.C. § 1395rr(b)(14)(B)(iv) (emphasis added), which reinforces that clauses (ii) and (iii)

[2] As for what "other things" clause (iv) allows, CMS doesn't say. But the import of its argument is that under clause (iv) it has virtually boundless authority—which, according to CMS, is wholly unreviewable because of the preclusion provision. This Court should be suspicious of such far-reaching claims. *See, e.g.*, *Mexichem Fluor, Inc. v. EPA*, 866 F.3d 451, 459 (D.C. Cir. 2017) (rejecting "boundless interpretation of [agency]s authority" as "border[ing] on the absurd").

cover drugs, while clause (iv) speaks to non-drug items (like diagnostic laboratory tests) that fall outside clause (i). Only Plaintiffs' reading makes sense of the whole statute.

CMS's reading of clause (iv), by contrast, would render clauses (ii) and (iii) superfluous. Under CMS's reading, Congress choice to define only certain drugs—and certain oral drugs in particular—as "renal dialysis services" in clauses (ii) and (iii) would be immediately superseded in the very next clause of the very same sentence by a category that covers all drugs that treat ESRD, including all oral-only ones. If that is right, there would have been "scant reason for Congress to provide any specific examples at all" in clause (ii) or (iii), which would become "an elaborate pumpfake." *Fischer v. United States*, 603 U.S. 480, 490 (2024). But construing clause (iv) that way gets standard statutory analysis "'exactly backwards,' eliminating specific terms because of broad language that follows them, rather than limiting the broad language in light of narrower terms that precede it." *Id.* (citation omitted).

CMS attempts to distinguish *Fischer* by claiming that it concerned a "residual phrase[] when the identified action sought to be swept in through the residual clause was too different in kind from the enumerated agency action[]." GB59-60. But *Fischer* is not so cabined; it rested on general principles of statutory interpretation squarely applicable here. The key point is that "a general phrase can be given a more

focused meaning by the terms linked to it," which "ensures—regardless of how complicated a sentence might appear—that none of its specific parts are made redundant by a clause literally broad enough to include them." *Fischer*, 603 U.S. at 488; *see* OB45-46. CMS's reading flouts this foundational rule.

CMS claims that clause (iv) "addresses a different subset of drugs than (B)(ii) and (B)(iii)," arguing that it addresses drugs for which separate payment was *not* made "before the application of this paragraph" in subpart (B)(iii)—i.e., future drugs. GB58-59. But that just underscores the problem with CMS's reading. Why would Congress carefully write subpart (B)(iii) to cover drugs before that date (except for "oral equivalent forms") and then write (B)(iv) to cover all drugs after that? The Government has no answer.

Moreover, the Government's theory is incompatible with its own reading of (B)(iii), under which Congress purportedly *did* address future drugs in that provision, supposedly deciding to count as "renal dialysis services" only those that are the "oral equivalent form" of biologicals or injectable/intravenous drugs on the market before 2011. But if Congress specifically thought about future drugs in clause (iii) and intentionally included only some, then reading clause (iv) as the provision by which Congress sought to address future drugs cannot be right. *Cf. Fischer*, 603 U.S. at 490.

"Includes." The opening language of subparagraph (B) states that "[f]or purposes of this paragraph, the term 'renal dialysis services' *includes*" the four enumerated categories. 42 U.S.C. § 1395rr(b)(14)(B) (emphasis added). CMS claims that, "to the extent that there might be concern about whether XPHOZAH and other oral-only drugs fit neatly into the subparagraph (B) clauses," the use of the word "'includes'" saves it. GB40-41. But "includes" is not an invitation to undo Congress's chosen definition of "renal dialysis services." OB52-55.

Both the statute and CMS's regulatory guidance reinforce that conclusion. Importantly, Congress provided that bundled payment should be made "for renal dialysis services (*as defined in subparagraph (B)*)," 42 U.S.C. § 1395rr(b)(14)(A)(i) (emphasis added)—not as that definition was enlarged or otherwise altered by CMS. The overall statutory text thus counsels strongly against treating the four categories set forth by Congress in subparagraph (B) as non-exhaustive. CMS itself contemporaneously viewed subparagraph (B) as setting forth "a comprehensive definition," *see* 75 Fed. Reg. at 49040, not one that Congress would have expected CMS to expand.

An agency cannot use language like "includes" to "redefine or otherwise avoid specific requirements" in the statutory language. *Fin. Plan. Ass'n v. SEC*, 482 F.3d 481, 489 (D.C. Cir. 2007). Even where "includes" sets forth examples, unenumerated items "must fit that same mold." *United States v. Brock*, 94 F.4th 39,

57 (D.C. Cir. 2024). CMS nowhere mentions *Financial Planning Association* or *Brock*, but these binding precedents demonstrate that "includes" cannot bear the weight of CMS's limitless interpretation.

"Vaccines." Subparagraph (B) also provides that "renal dialysis services" "does not include vaccines." 42 U.S.C. § 1395rr(b)(14)(B). CMS emphasizes that Congress expressly excluded vaccines but did not also say that "renal dialysis services" "does not include oral-only drugs." GB41-42. But Congress's carve-out for vaccines recognizes that vaccines could otherwise fall within the scope of subparagraph (B). By contrast, such an exclusion is unnecessary for oral-only drugs, which already fall outside subparagraph (B)'s scope. *See Harbor Ins. Co. v. Omni Constr., Inc.*, 912 F.2d 1520, 1524 (D.C. Cir. 1990) (If term "did not otherwise include" an item, then its "exclusion would be meaningless.").

In addition, CMS has the fundamental principle backwards: The exclusion of one thing does not mean the *inclusion* of all others. *Cf.* Antonin Scalia & Brian Garner, *Reading Law: The Interpretation of Legal Texts* 107 (2012) ("Negative-Implication Canon[:] The expression of one thing implies the exclusion of others."). Put otherwise, the absence of an express limitation does not confer power on CMS to act. Rather, CMS must point to an affirmative grant of authority from Congress empowering it to expand on MIPPA's definition of renal dialysis services. *Mozilla Corp. v. FCC*, 940 F.3d 1, 75 (D.C. Cir. 2019) ("[A]n 'agency may not confer power

on itself' …." (citation omitted)). Congress did not do so, and CMS cannot "change basic decisions made by Congress." *Am. Bankers Ass'n v. SEC*, 804 F.2d 739, 753-54 (D.C. Cir. 1986).

B. CMS's Appeal To Ambiguous Subsequent Enactments Cannot Authorize A Departure From The Statute's Plain Meaning

Lacking textual justification for its inclusion of oral-only drugs, CMS tries to support its reading of MIPPA with later action by different Congresses. CMS claims (at 43) that "all congressional action in this area leads inexorably to the conclusion that Congress … approved CMS's decision" to include oral-only drugs in the bundle. Far from it.

To start, CMS glosses over the fact that the congressional history evinces *concern* with CMS's current construction, not approval. As Plaintiffs explained, one year after the enactment of MIPPA, the House of Representatives introduced a bill that would have amended subpart (B)(iii) specifically to "includ[e] oral drugs that are not the oral equivalent of an intravenous drug (such as oral phosphate binders and calcimimetics." America's Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 1232(C)(2)(b)(1) (2009); *see* OB42-43. That Congress considered but did not adopt a proposal to specifically include oral-only drugs in the bundle is surely relevant—especially because this is the most contemporaneous and on point consideration of whether (B)(iii) includes oral-only drugs. CMS claims that this unenacted bill "sheds no light on what the unamended text means," GB49-51, and

that it is equally plausible that Congress saw the amendment as unnecessary. But that seems unlikely given the substantial controversy over whether CMS's oral-only policy accorded with MIPPA. *See* 75 Fed. Reg. at 49039. In any event, that response by a nearly contemporaneous Congress cuts strongly against the inferences that CMS tries to draw from later congressional action.

CMS points to actions by which Congress delayed the implementation of its oral-only drug policy, directed the Government Accountability Office ("GAO") to study the issue, and ordered CMS to monitor certain measures. GB44-47. It then says that "[t]hese directives would make little sense if CMS lacked statutory authority to include oral-only drugs in the bundled payment rate." GB47. Not so.

To be sure, these subsequent actions demonstrate congressional *awareness* of CMS's oral-only drug policy, but they certainly do not "inexorably" show congressional *approval*. *Contra* GB43. An equally plausible inference is that no congressional majority existed to endorse or reject CMS's policy, leaving Congress with only the option of half-measures. Regardless, later congressional actions are more consistent with *Plaintiffs*' reading of the statute. For instance, one enactment directed CMS to establish a process for adding new injectable and intravenous products into the bundled payment system. Pub. L. No. 113-93, § 217(c), 128 Stat. at 1062 (codified at 42 U.S.C. § 1395rr note). That better accords with Plaintiffs'

reading of subpart (B)(iii), not the Government's (which would exclude new injectable and intravenous products).

In any event, the later congressional enactments on which the Government relies express skepticism of CMS's policy. Delaying the effective date of CMS's oral-only drug policy multiple times over, monitoring the potential risks through the GAO, and setting up safeguards is hardly a ringing endorsement of CMS's actions. Rather, it shows only that Congress was suspicious of CMS's policy. *See, e.g.*, *Connolly v. PBGC*, 475 U.S. 211, 215 (1986) (noting "Congress delay[ed] the effective date" and "directed [an entity] to prepare a report analyzing the problems" because it "'became concerned'" (citation omitted)); *Nichols v. United States*, 260 F.3d 637, 644 (6th Cir. 2001) (noting Congress "thought further review was necessary" and "therefore delayed implementation of that provision").

While different inferences can be drawn from the legislative history, what matters is that Congress has never expressly agreed with CMS's policy, let alone purported to address or modify MIPPA's statutory definition of "renal dialysis services."[3] As a result, those later enactments cannot control MIPPA's interpretation. *See, e.g.*, *Ashton v. Pierce*, 716 F.2d 56, 63 (D.C. Cir. 1983)

[3] To the extent that CMS suggests that this lack of amendment favors its own interpretation, *see* GB47-48, that is off-base. The case CMS cites refers to a "longstanding administrative interpretation," *see CFTC v. Schor*, 478 U.S. 833, 846 (1986), but here CMS argues that its interpretation has never been "applicable" for oral-only drugs, *see supra* at 10-15.

(Congress cannot indirectly "ratify an administrative interpretation that is contrary to the plain meaning of the Act.").

C. Including Oral-Only Drugs In The Bundle Will Harm Patients

CMS's last resort is to appeal to policy, claiming that including oral-only drugs in the bundle will control costs, promote operational efficiency, and provide broader access to oral-only drugs. GB43-44. But CMS stands alone here. Dozens of organizations representing every component of the kidney-care community *opposed* the inclusion of oral-only drugs in the bundle as harmful to patients, *see* 75 Fed. Reg. at 49038, and organizations representing a broad range of ESRD patients and providers are Plaintiffs in this case.

For good reason. In practice, CMS has set the bundled payment rate at an amount that barely covers a dialysis facility's cost of care, and sometimes fails to do even that. JA12 (Compl. ¶ 9); JA99 (Williams Decl. ¶ 66 (Dkt. 14-3)); *see* OB9-11. Real-world evidence shows that access to novel drugs drops precipitously once those drugs are included in the bundle. OB40-42 & n.10. And—as the reports commissioned by Congress show—these burdens fall heaviest on patients from minority, rural, and low-income backgrounds, as well as small dialysis providers. *See* JA80-83 (Puckrein Decl. ¶¶ 9-31 (Dkt. 14-2)); JA75 (Clynes Decl. ¶¶ 32-35 (Dkt. 14-1)); 75 Fed. Reg. 55760, 55827 (July 5, 2024); GAO, GAO-11-365, *End-Stage Renal Disease: CMS Should Assess Adequacy of Payment When Certain Oral*

Drugs Are Included and Ensure Availability of Quality Monitoring Data 17 (2011), https://www.gao.gov/assets/gao-11-365.pdf (small dialysis providers noting that "weaker purchasing power" "would make it difficult for them to negotiate competitive prices"); GAO, GAO-24-106288, *End-Stage Renal Disease: CMS Plans for Including Phosphate Binders in the Bundled Payment* 19 (2023), https://www.gao.gov/assets/870/864145.pdf (similar).[4]

CMS claims that Plaintiffs' "underutilization concerns" are overblown. GB51-52. Yet CMS never responds to Plaintiffs' real-world examples regarding Parsabiv and Korsuva. Adding Parsabiv to the bundle dropped its usage from over 10% to less than 1%, and Korsuva's manufacturer terminated a phase 3 clinical trial for an oral form once the injectable form was moved into the bundle. OB41; *see* JA100-02 (Williams Decl. ¶¶ 75, 80).

CMS also trumpets the Transitional Drug Add-on Payment Adjustment ("TDAPA") as allaying Plaintiffs' concerns. GB51. But TDAPA is no answer—it does not provide sufficient reimbursement, and its two-year limitation deters use even within that period. Recent experience confirms as much: less than 1% of

[4] The March 2011 GAO report resulted from the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. X, subtitle C, § 10336, 124 Stat. 119, 974 (2010). The November 2023 report resulted from Pub. L. No. 112-240, tit. VI, subtit. C, § 632(d), 126 Stat. 2313, 2354-55 (2012), as amended by the GAO Mandates Revision Act of 2016, Pub. L. No. 114-301, § 3(c), 130 Stat. 1514, 1515 (2016).

Medicare ESRD patients ultimately accessed Korsuva during its two-year TDAPA period despite evidence demonstrating that between 30-40% of ESRD patients suffer from the condition that Korsuva treats. JA151 (Williams Suppl. Decl. ¶¶ 11-13 (Dkt. 20-1)). And more than 40% of Medicare ESRD patients have transitioned to plans for which dialysis facilities do not receive any TDAPA payments. JA151 (Williams Suppl. Decl. ¶ 13).

Finally, CMS argues that including XPHOZAH in the bundle makes sense because it can be "an alternative or additional mode of treatment" to phosphate binders that are already in the bundle. GB48-49. But that just begs the question, because phosphate binders are oral-only drugs too, JA144-45 (Williams Decl. Ex. 7 at 1-2 (Dkt. 14-10))—so they do not fall within the bundle on a proper understanding either. At any rate, XPHOZAH is not an "equivalent form" of phosphate binders; instead of binding to excess phosphate, it blocks phosphate absorption at the primary cellular pathway. OB18-19.

III. XPHOZAH IS NOT A RENAL DIALYSIS SERVICE

Even if this Court concludes that oral-only drugs can be included in the bundle as a general matter, XPHOZAH cannot be because it is not a drug "furnished to individuals for the treatment of end stage renal disease." 42 U.S.C. § 1395rr(b)(14)(B)(iii)-(iv); 42 C.F.R. § 413.171(3)-(4). XPHOZAH treats hyperphosphatemia, not ESRD. OB55-57.

CMS claims (at 62-63) that treating hyperphosphatemia is the same as treating ESRD. But in ordinary language, treating one disease (even if it is related to another disease) is different than treating that other disease. "Treatment" is condition-specific; it means "[m]anagement in the application of remedies." *Treatment*, Oxford English Dictionary (last modified June 2024), https://www.oed.com/dictionary/treatment_n?tab=meaning_and_use#17741134 (login required). XPHOZAH is not a remedy applied to manage ESRD; it is instead a remedy aimed at hyperphosphatemia by reducing phosphate in the blood. *See* OB17-19.

CMS also argues (at 64-65) that clause (iii) should be read to cover drugs that treat conditions associated with ESRD because clause (ii) covers ESAs and ESAs do not, according to CMS, directly treat ESRD. But there are good reasons for why Congress thought that ESAs "treat[]" ESRD. ESAs are labeled and indicated for "the treatment of anemia *due to* chronic kidney disease," which indicates a causal link. *See, e.g.*, Epogen FDA Label (last revised Apr. 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103234s5378lbl.pdf; (emphasis added). Dialysis itself causes blood loss that may necessitate treatment with ESAs. *See, e.g.*, Nat'l Kidney Foundation, *Anemia and Chronic Kidney Disease*, https://www.kidney.org/kidney-topics/anemia-and-chronic-kidney-disease (last visited Mar. 26, 2025). And patients on ESAs are injected with those drugs "[a]t nearly every dialysis treatment." GAO, GAO-07-77, *End-Stage Renal*

Disease: Bundling Medicare's Payment for Drugs with Payment for all ESRD Services Would Promote Efficiency and Clinical Flexibility 3 (2006), https://www.gao.gov/assets/gao-07-77.pdf ("GAO 2006 Report"). By contrast, phosphate-lowering therapies like XPHOZAH *cannot* be used just prior to or during dialysis. *See* OB19. XPHOZAH is indicated "to reduce serum phosphorus in adults *with* chronic kidney disease (CKD)," which suggests correlation rather than causation. JA103-13 (Williams Decl. Ex. 1 (Dkt. 14-4)) (emphasis added). And a substantial number of ESRD patients do not have hyperphosphatemia, while some patients have hyperphosphatemia but not ESRD. OB17-18.

Plus, Congress had previously provided that ESAs "shall *not* be a dialysis service" under the then-existing payment system. Omnibus Budget Reconciliation Act, Pub. L. No. 101-508, § 4201(c), 104 Stat. 1388 (1990) (emphasis added). That resulted in annual costs of "$2 billion, accounting for more than two-thirds of Medicare payments for all separately billable drugs." GAO 2006 Report 2; *see also id.* at 10; 75 Fed. Reg. at 49160. Given that history, Congress had particular need to specifically identify ESAs as "renal dialysis services" in MIPPA. 42 U.S.C. § 1395rr(b)(14)(B)(ii). Congress's express inclusion of ESAs highlights its decision to exclude other drugs from subparagraph (B) that were then available—such as oral-only drugs.

As for drugs that treat diabetes, cardiac conditions, and hypertension, CMS has little answer other than "trust us" when it comes to those drugs' exclusion from the bundle. *See* GB65. CMS does not tie its policy to exclude these drugs to any language in the statute, and its expansive interpretation of "treatment" necessarily includes them. Coupled with its claim to unreviewability, CMS's assertions are cold comfort for providers, manufacturers, and patients.

CONCLUSION

For the foregoing reasons, the district court's judgment should be reversed and summary judgment granted to Plaintiffs-Appellants.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with Federal Rule of Appellate Procedure 32(f) and (g), because it contains 6,498 words.

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word and Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on April 10, 2025, I electronically filed the foregoing brief with the United States Court of Appeals for the District of Columbia Circuit through the Court's CM/ECF system. All parties are represented by registered CM/ECF users and will be served by the CM/ECF system.

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